

| General Information                |                             |
|------------------------------------|-----------------------------|
| EudraVigilance Local Report Number | EU-EC-10012423110           |
| Sender Type                        | Regulatory authority        |
| Sender's Organisation              | EEA Regulator               |
| Type of Report                     | Spontaneous                 |
| Primary source country             | European Economic Area      |
| Reporter's qualification           | Non-Healthcare Professional |
| Case serious?                      | Yes                         |

| Patient   |                             |     |
|-----------|-----------------------------|-----|
| Age Group | Age Group (as per reporter) | Sex |

| Reaction / Event               |          |                    |                          |
|--------------------------------|----------|--------------------|--------------------------|
| MedDRA LLT                     | Duration | Outcome            | Seriousness <sup>1</sup> |
| Cardiac arrest                 |          | Recovered/Resolved | hospital., other         |
| Renal insufficiency aggravated |          | Unknown            | hospital., other         |
| Death                          | 0.0 Days | Fatal              | death., other            |

| Drug Information  |                         |          |      |                   |              |
|-------------------|-------------------------|----------|------|-------------------|--------------|
| Role <sup>2</sup> | Drug                    | Duration | Dose | Units in Interval | Action taken |
| S                 | COMIRNATY - TOZINAMERAN |          |      |                   |              |

| Drug Information (cont.) |                         |                       |             |                 |
|--------------------------|-------------------------|-----------------------|-------------|-----------------|
| Info <sup>3</sup>        | Drug                    | Indication            | Pharm. Form | Route of Admin. |
|                          | COMIRNATY - TOZINAMERAN | COVID-19 immunisation |             |                 |

1

Seriousness: **death**=results in death; **life threat.**=life threatening; **hospital.**=requires hospitalization/prolongation of hospitalization; **disability**=results in disability/incapacity; **congen.**=congenital anomaly/birth defect; **other**=other medically important information; **(blank)**=non-serious

2

Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=not administered

3

Additional Information on Drug: **1**=Counterfeit; **2**= Overdose; **3**=Drug taken by the father; **4**=Drug taken beyond expiry date; **5**=Batch and lot tested and found within specifications; **6**=Batch and lot tested and found not within specifications; **7**=Medication error; **8**=Misuse; **9**=Abuse; **10**=Occupational exposure; **11**=Off label use; **(blank)** =no additional information

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Page 1 of 1